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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,299	10/16/2001	Timothy R. Ryan	M190.137.101	7830

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

7

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,299

Applicant(s)

RYAN ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 30-33 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 30-33 and 37-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Arguments

1. Applicant's arguments filed 7-7-03 have been fully considered but they are not persuasive.

2. First, with regard to amended claim 1, Applicant states Wright '296 and Meyers '397 do not disclose "a sheath having a shape conforming to a shape of the eyelets." (claim 1). Examiner disagrees. Wright clearly shows in figure 2 eyelets disposed within the sheath and lines 48 of col. 13 through line 16 of col. 14 describes a flexible sheath that is sewn around the stiffening element. Myers is argued for similar reasons. Additionally, the newly added limitation of claim 1 reads on the sheath having a round profile conforming to the round wire profile of the stiffening element eyelets in both of Meyer and Wright.

3. Second, with regard to amended claim 10, Applicant states Wright and Meyers do not teach marking indicating eyelet position. Regarding Meyers, Applicant contends that an eyelet is disposed outside of the sheath. Examiner disagrees. Figure 6B of Meyers shows 2 ends having eyelets within the sheath. And lines 16-20 of col. 4 teach a marking to indicate the position of the entire stiffener with respect to the sheath, which includes the eyelets. The intent of the marking is irrelevant. With regard to Wright, lines 45-49 of col. 15 describe a colored suture to indicate position of the stiffener. Again, the intent of the marking is irrelevant because the structure reads on the claim language.

4. Third, with regard to claim 16, Applicant argues that neither Wright nor Myers disclose manufactured saddle shape prosthesis. Examiner disagrees with Applicant because both Myers and Wright disclose completely flexible prostheses for conforming

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to a saddle shaped annulus and the claims do not differentiate between manufactured and implanted shapes.

5. Finally, with regard to claims 30-33, Applicant argues that Meyers and Wright do not teach a band having a thickness less than 3.0, 2.7, and 2.5mm. Examiner respectfully disagrees. The language of claims 30-32 reads "no greater than about 3.0 mm", "no greater than about 2.7mm", and "no greater than about 2.5mm", and furthermore Applicant's specification does not describe the range encompassed by "no greater than about" (see MPEP 2173.05(b)). With regard to the references, Meyers discloses in lines 45-49 of col. 3 the stiffener wire 28 to have a diameter of 0.75mm and using the measurement with figure 5 shows an overall thickness of about 2.25mm clearly less than 2.5mm. Wright et al. discloses in lines 63-66 of col. 14 the stiffener wire having a diameter of 0.028" or 0.7mm and using this measurement with figure 6 provides a vertical thickness of about 2.7mm which reads on "no greater than about 2.5mm" because the specification does not define the limits of "no greater than about" to be less than 10%, for example.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 1-3,9-13,15,16, 30-33, and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers US PN 5,716,397.

Myers discloses in figures 4 and 6F and line 46 of col. 2 through line 26 of col. 4 annuloplasty devices comprising a fabric sheath having position indicating markings such as colored suture and a radiopaque arcuate stiffening wire disposed within the sheath having a thickness less than about 2.5 mm and eyelets disposed at the ends. Figure 4 shows a stiffening element generally saddle shaped in a Z-plane and arcuate in X and Y planes. Furthermore, claims 2-3 recite intended use limitations, which do not structurally limit the annuloplasty band.

3. Claims 1-4,7,9-13,15,16, 30-33, and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. US PN 5,306,296.

Wright et al. discloses in figures 2 and line 48 of col. 13 through line 66 of col. 14 annuloplasty devices comprising a fabric sheath having position indicating markings such as colored suture and a radiopaque arcuate stiffening wire disposed within the sheath having a thickness less than about 2.5 mm and ends bent back on itself to form eyelets. Figure 4B shows a stiffening element generally saddle shaped in a Z-plane and arcuate in X and Y planes. Furthermore, claims 2-3 recite intended use limitations, which do not structurally limit the invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 as applied to claims 1,4,7 in the 102(b) rejection above, and further in view of Carpentier et al. US PN 5,061,277.

Wright et al. discloses an annuloplasty device meeting the structural limitations of claims 5, 6, and 8 as described above, but lacks the express disclosure of the stiffening element having the three particular radii of curvature and a silicon overmold. Carpentier et al. teaches in figures 1 and 3, lines 9-16 of col. 3, and line 57 of col. 3 through line 7 of col. 4 an annuloplasty device having a sheath and stiffening ring wherein the stiffening ring has the three particular radii of curvature (of claim 8) to properly fit the shape of the natural mitral valve, and furthermore adds a silicone overmold to make the band soft and compressible as well as more resilient.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath and stiffening element disclosed by Wright et al. by using the particular shape and overmold taught by Carpentier et al. in order to properly fit the shape of the natural mitral valve and make the band soft and compressible as well as more resilient.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 or Myers US PN 5,716,397 as applied to claim 1 in the 102(b) rejections above, and further in view of Loch et al. US PN 6,174,332.

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Wright et al. or Myers discloses an annuloplasty device meeting the structural limitations of claim 14 as described above, but lacks the express disclosure of the sheath being formed of biological tissue. Loch et al. teaches in lines 44-57 of col. 3 an annuloplasty ring having a sheath made of biological tissue to provide sufficient biocompatibility.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath disclosed by Wright et al. or Myers by using biological tissue as taught by Loch et al. in order to provide sufficient biocompatibility.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number

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is 703-305-0316. The examiner can normally be reached on Tue-Fri 8:00-6:30 (Every Monday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM
September 21, 2003



**CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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